



# UNITED STATES PATENT AND TRADEMARK OFFICE

*cen*

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,353	03/16/2004	Yasuhiro Watanabe	04-218	3622
<div>34704      7590      12/10/2007 BACHMAN &amp; LAPOINTE, P.C. 900 CHAPEL STREET SUITE 1201 NEW HAVEN, CT 06510</div>				
			EXAMINER MUI, CHRISTINE T	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 12/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/802,353

Applicant(s)

WATANABE ET AL.

Examiner

Christine T. Mui

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 16 October 2007 have been fully considered but they are not persuasive.

2. In reference to claims 1-12, the applicant suggests that the reference Coleman does not disclose or suggest a sealing protrusion that is formed with a device body. It is disclosed by Coleman that the miniaturized integrated analytical test container has sealing means that can be an pressure sensitive adhesive that seals a web portion of the exterior wall of the container that is film. Colman also discloses a closure member which may be a strippable tape or film can be removed to establish communication between the container exterior and the cuvette. Furthermore, a uniquely configured rod-like closure may be employed as all or part of the sealing means. The rod is preferably provided with seal displacing or fracturing means at the inner free end (see column 2, lines 69-72, column 5, lines 66-69, Figures 1-3, claim 3). It is interpreted by the examiner that the strippable tape or film on the exterior of the test container is a protrusion that creates a projection or a bulge away from the surface of the container. One can layer multiple pieces of tape or film on the vent of the device preventing communication with the outside environment creating a larger protrusion or bulge that projects itself from the surface of the container.

3. For reasons given herein the previous rejections are hereby maintained.

### ***Claim Objections***

4. Claims 13-18 are objected to because of the following informalities:

5. In claims 13-18, in the instance where it reads "thin connecting portion being capable of removed" probably should read "thin connecting portion capable of being removed". Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 3,799,742 to Coleman (herein referred Coleman).

8. Regarding claims 1-2 and 4, the reference Coleman discloses a miniaturized integrated analytical test container with an analytical test container with an elongated body with a passageway or conduits that extends through the end wall that connects the reception chamber with the exterior of the container. At the position below the separation chamber are first and second cuvettes. There is a closure member at an exterior opening of the container made of strippable tape or film that when removed communication is established between the container exterior a second cuvette. Furthermore, a uniquely configured rod-like closure may be employed as all or part of the sealing means. The rod is preferably provided with seal displacing or fracturing means at the inner free end (see column 2, lines 69-72, column 5, lines 9, 28-30, 57-59 and 66-69, Figures 1-3, claim 3). It is interpreted by the examiner that the strippable tape or film on the exterior of the test container is also a protrusion that creates a projection or a bulge away from the surface of the container. One can layer multiple pieces of tape or film on the vent of the device preventing communication with the

outside environment creating a larger protrusion or bulge that projects itself from the surface of the container. Furthermore, in initiating use of the miniaturized test container, access to the reception chamber is obtained through a passage way after the removal of the passageway seal or closure (see column 5, lines 33-36). Coleman discloses the claimed invention except for specifically stating that the passageway seal or closure is an integral part with the device body the fluid moves through the device due to capillarity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sealing protrusion formed so as to be integrated with the device body, since it has been held that forming in one piece of an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the diameter of the passageways of the test container that samples that are being mixed can flow through the device due to the adhesive or cohesive properties of the sample and the surface tension of the solid of the container to create capillary flow of the sample within the container or device.

9. Regarding claim 3, the reference Coleman discloses a test container that has multiple cuvettes and multiple exhaust vents that are provided with strippable gas and liquid permeable tape closures that overlies permanently secured opening covers. A uniquely configured rod-like closure may be employed as all or part of the sealing means. The rod is preferably provided with deal displacing or fracturing means at the inner free end. Furthermore, in initiating use of the miniaturized test container, access

to the reception chamber is obtained through a passageway after the removal of the passageway seal or closure (see column 2, lines 69-72, column 5, lines 33-36, column 14, lines 73-75 and column 15, lines 1-5 and Figure 25). Coleman discloses the claimed invention except for specifically stating that the passageway seal or closure is an integral part with the device body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sealing protrusion formed so as to be integrated with the device body, since it has been held that forming in one piece of an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1993).

10. Regarding claims 5-6, the reference Coleman discloses an analytical testing device with a plurality of chambers where there are a plurality of conduits in the test device which are connected with each other and to a chamber which has a cover on the vent of the chamber made of an impermeable tape to initiate flow when opened. A uniquely configured rod-like closure may be employed as all or part of the sealing means. The rod is preferably provided with deal displacing or fracturing means at the inner free end. Furthermore, in another embodiment, the analytical testing device is arranged so that the reception chamber at one end of the device with a stopper providing closure to the environment is at one end of the test device that is in communication with the other chambers throughout the device (see column 2, lines 69-72, column 5, lines 33-36, column 21, lines 56-60 and 22, Figure 36). It is interpreted by the examiner that the strippable tape or film on the exterior of the test container is a

protrusion that creates a projection or a bulge away from the surface of the container. One can layer multiple pieces of tape or film on the vent of the device preventing communication with the outside environment creating a larger protrusion or bulge that projects itself from the surface of the container which does not change the functionality if there was a flange or rod protruding from the surface of the device. Furthermore, in initiating use of the miniaturized test container, access to the reception chamber is obtained through a passage way after the removal of the passageway seal or closure (see column 5, lines 33-36). Coleman discloses the claimed invention except for specifically stating that the passageway seal or closure is an integral part with the device body the fluid moves through the device due to capillarity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sealing protrusion formed so as to be integrated with the device body, since it has been held that forming in one piece of an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the diameter of the passageways of the test container that samples that are being mixed can flow through the device due to the adhesive or cohesive properties of the sample and the surface tension of the solid of the container to create capillary flow the sample within the container or device.

11. Regarding claims 7-10, the reference Coleman discloses an analytical testing container with an enter header and a stopper for delivery to a series of chambers that

provide the chambers with substantially the same quantities of sample that is connected to the reception chamber with a vent that is capable of being open to the outside. The stopper can be removed so that the reception chamber is able to have communication with the container exterior. Branching from the enter header there are a plurality of branch conduits connected to chambers to allow flow of a liquid or gas and to a vent opening that can be covered by an impermeable tape to initiate flow when removed (see column 21, lines 56-75 and column 22, lines 1-51 and Figure 25 and 36). Coleman discloses the claimed invention except for specifically stating that the passageway seal or closure is an integral part with the device body the fluid moves through the device due to capillarity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sealing protrusion formed so as to be integrated with the device body, since it has been held that forming in one piece of an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1993).

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made alter the diameter of the passageways of the test container that sample that are being mixed can flow through the device due to the adhesive or cohesive properties of the sample and the surface tension of the solid of the container to create capillary flow of the sample within the container or device.

12. Regarding claims 11-12, the reference Coleman discloses a miniaturized integrated analytical test container used to test blood glucose, urea, total protein and additional tests. The miniaturized analytical test container (Figure 36) has a container



with a fluid header that is formed in the body to allow flow of a fluid due to contact of the fluid with the solid part of the container that is distorted, elevated or depressed to form capillary flow action. The test container has multiple openings (Figure 36, 872, 886, 896) with a gas and liquid impermeable tape (Figure 36, 874, 888, 898) over each opening to initiate flow. The analytical test container is capable to have fluids injected into the openings (896 and 886) and sealed with the impermeable tape (898 and 888). The fluids are then collected in the cuvettes (Figure 36, 882 and 892) and mixed in cuvette (882) when a tape (888) is removed and tape (898) is sealed. The mixed fluids in cuvette (882) are then capable of being fed to cuvette (868) at the end of the flow passage (864) by closing (898 and 888) and opening the tape (874) (see column 21, lines 50-75 and column 22, line 1-75). Coleman discloses the claimed invention except for specifically stating that the passageway seal or closure is an integral part with the device body the fluid moves through the device due to capillarity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sealing protrusion formed so as to be integrated with the device body, since it has been held that forming in one piece of an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1993). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the diameter of the passageways of the test container that samples that are being mixed can flow through the device due to the adhesive or cohesive properties of the sample and the

surface tension of the solid of the container to create capillary flow the sample within the container or device.

13. Regarding claims 13-18, the reference Colman discloses a closure member at an exterior opening of the container made of strippable tape or film that when removed communication is established between the container exterior a second cuvette in a miniaturized analytical test container. A uniquely configured rod-like closure may be employed as all or part of the sealing means. The rod is preferably provided with deal displacing or fracturing means at the inner free end (see column 2, lines 69-72, column 5, lines 9, 28-30, 57-59 and 66-69, Figures 1-3, claim 3). It is interpreted by the examiner that the strippable tape of film that is disposed on the opening of the passage way between the inner portion of the container and the outside environment is a thin connecting portion. Coleman discloses the claimed invention except for specifically stating that the passageway seal or closure is an integral part with the device body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sealing protrusion formed so as to be integrated with the device body, since it has been held that forming in one piece of an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1993).

***Allowable Subject Matter***

14. Claims 19-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. A rod shaped protrusion where there is a flange –shaped thin connecting portion that is capable of being broken off on a fluid handling device promoting capillary action of fluid in a device is not found in the prior art.

***Conclusion***

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine T. Mui whose telephone number is (571) 270-3243. The examiner can normally be reached on Monday-Friday 8-5; Alternate Friday.

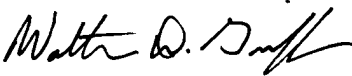
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:  
10/802,353  
Art Unit: 1797

Page 11

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

  
WALTER D. GRIFFIN  
SUPERVISORY PATENT EXAMINER